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Testing Different Biphasic Waveforms and Capacitances: Effect on Atrial Defibrillation Threshold and Pain Perception

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Objectives. The goal of this study was to compare the effect of different tilts and capacitances for biphasic shocks on atrial defibrillation efficacy and pain threshold.

Background. Although biphasic shocks have been shown to be superior to monophasic shocks, the effect of tilt and capacitance on atrial defibrillation success and pain perception has not been studied in patients.

Methods. Atrial defibrillation threshold (DFT) testing was performed using a right atrial appendage/coronary sinus lead configuration in 38 patients with a history of paroxysmal atrial fibrillation undergoing an invasive electrophysiologic study. Biphasic waveforms with 40%, 50%, 65%, 80%, 30%/50% and 40%/50% were tested randomly in 22 patients (Group 1). In 16 patients (Group 2), a 65% tilt waveform with 50- and 120-μF capacitance was tested. Before sedation, pain sensation was graded by 15 patients in Group 1 after delivery of a 0.5-J shock and by 10 patients in Group 2 after two 1.5-J shocks with 50- and 120-μF capacitance were delivered.

Results. The DFT energy for the 50% tilt waveform was significantly lower than the 65%, 80% and 30%/50% tilt waveforms. The 40%/50% tilt waveform provided slightly lower energy requirements than the 50% tilt waveform. Nine patients (60%) described the 0.5-J shock as very painful, and four (26.6%) complained of slight pain. The 50-μF capacitor lowered energy requirements compared with the 120-μF capacitor. Six patients (60%) perceived the 1.5-J 50-μF capacitor shock as more painful, whereas three (30%) perceived both shocks as equally painful.

Conclusions. Biphasic waveforms with 50% tilt in both phases and a smaller tilt in the positive phase than that in the negative phase (40%/50%) provided a decrease in energy requirements at atrial DFT. In addition, stored energy was reduced by biphasic shocks with 50-μF capacitance compared with 120-μF capacitance. Despite the reduction in energy requirements, shocks <1 J continued to be perceived as painful in the majority of patients.

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Atrial fibrillation is the most complex and the most common of all the tachyarrhythmic disorders. For the vast majority of patients with atrial fibrillation, the pharmacologic approach remains the mainstay of therapy. However, the safety and efficacy of antiarrhythmic drugs have not proved satisfactory, with most patients experiencing at best only moderate control of atrial fibrillation.

As a result, in the past 2 years a great deal of effort has been devoted to the development of alternative, nonpharmacologic therapies for patients with atrial fibrillation. With the success of the implantable cardioverter-defibrillator for ventricular arrhythmias, devices capable of recognizing and terminating atrial fibrillation are now being developed. Although clinical studies have shown that internal atrial defibrillation can be achieved with relatively low energies, a major challenge in the clinical application of this technology is the need to obtain termination of atrial fibrillation with energy below the pain threshold because most patients may not be willing to accept a painful shock for a usually well tolerated hemodynamic and often chronic disorder. Although biphasic shocks show superiority with respect to monophasic shocks, limited information is available regarding all various waveforms and other variables such as capacitance. We therefore, investigated the clinical efficacy of various tilt-based biphasic pulses and smaller capacitances (50 μF) on atrial defibrillation success and the effect of low energy biphasic shocks on pain perception.

Methods

Patients. The study included 38 patients undergoing invasive electrophysiologic study for atrioventricular node ablation, atrial flutter ablation and evaluation of ventricular arrhythmias. Patients were considered eligible for the study if they had a previous history of paroxysmal atrial fibrillation. Before the study verbal and written consent were obtained according to the guidelines of the Veterans Affairs Medical Center Human Research Committee. The study patients were classified into two groups that underwent different protocols. The clinical and demographic data of the two groups are shown in Table 1. All antiarrhythmic medications were discontinued at least 5 half-lives before the study.

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Table 1. Clinical and Demographic Data of Two Patient Groups

	Group 1 (n = 22)	Group 2 (n = 16)
Age (yr)	65 ± 8	62 ± 11
Range	59–71	56–74
Male/female	22/0	16/0
LVEF (%)	44 ± 12	47 ± 11
IHD	16	3
IDC	0	3
Hx of vent. arrhythmias	12	3

Data presented are mean ± SD, range or number of patients. Hx = history; IDC = idiopathic dilated cardiomyopathy; IHD = ischemic heart disease; LVEF = left ventricular ejection fraction; vent. = ventricular.

Defibrillation lead system. Custom-made 6F catheters (Electro-catheter Inc.) were used to deliver the energy. Each catheter consisted of nine 5-mm platinum electrodes with an interelectrode distance of 2 mm. All electrodes were connected together and resulted in a total surface area of 133 mm^2. The catheters were placed under fluoroscopic guidance in the right atrial appendage using the left subclavian vein approach and in the coronary sinus through the right internal jugular vein. An additional 6F quadripolar catheter was advanced in the right ventricular apex through the right femoral vein for shock delivery synchronized to the right ventricular electrogram and for cardiac pacing if postshock bradycardia occurred. In 15 patients undergoing testing for cardioverter-defibrillator implantation, the right ventricular defibrillation electrode (Transvene, model 6966, Medtronic Inc.) was used for synchronization and sensing. An additional quadripolar catheter was placed in the right atrium to induce atrial fibrillation and to ensure adequate fibrillatory activity before delivering a shock. To deliver biphasic waveforms, the defibrillation catheters were interfaced with an external defibrillator (Medtronic model 2394) that delivered a truncated exponential shock with programmable tilt in both the positive and negative phases. Tilt was defined by the amount of voltage decay at the time of truncation. Isolated peak voltage, current, stored energy and impedance for each waveform shock and phase were obtained through a Medtronic model 2394004 breakout box that was connected between the defibrillator and the patient cable. The total capacitance used to deliver the biphasic pulses was 50 or 120 μF, or both, according to the study protocol.

Atrial defibrillation testing. Atrial fibrillation was induced either by rapid burst pacing or by 60-Hz alternating current delivered through the right atrial catheter. After a minimum of 30 s of established atrial fibrillation, R wave synchronized shocks were delivered to the atria. The energy of the first shock was programmed at 0.5 J. If unsuccessful, the energy of the subsequent shock was increased by 0.5-J steps until atrial fibrillation was terminated. Shocks were separated by at least 30 s. Before shocks were delivered, appropriate ventricular sensing through the Medtronic external defibrillator was documented. The *atrial defibrillation threshold* for each biphasic waveform was defined as the lowest energy that successfully terminated atrial fibrillation. After successful termination of atrial fibrillation, the arrhythmia was induced again after a rest period of 2 to 3 min. If hemodynamic instability was observed during atrial fibrillation or shocks resulted in ventricular arrhythmias that required external cardioversion, a rest period of 5 min or return of normal hemodynamic status was allowed before reinduction of atrial fibrillation.

Group 1. Twenty-two patients were enrolled in this part of the study. In each patient the defibrillation threshold was randomly determined by using six biphasic waveforms. The exponential truncated biphasic waveforms comprised 40%, 50%, 65% and 80% equal tilt in both the positive and negative phases and two waveforms comprising a positive phase tilt of 30% and 40%, respectively, with a constant negative phase tilt of 50%. Each phase was separated by 0.2 ms. Biphasic waveforms were produced to emulate a single capacitor discharge so that the leading edge voltage of the second phase was equal to the trailing edge voltage of the first phase. For each phase, stored energy, peak voltage, current and impedance were obtained.

Group 2. Sixteen patients were included in this portion of the study. Patients in Group 2 underwent testing by delivery of a 65% fixed-tilt equiphasic waveform that differed by the total capacitance used. In each patient, the 50- and 120-μF biphasic waveforms were randomly tested. Energy, voltage, current, impedance and total pulse width were recorded.

Pain threshold determinations. Fifteen patients in Group 1 received a 0.5-J shock before sedation was achieved using a 65% fixed-tilt biphasic pulse with 120-μF capacitance. After the shock, the patients were asked to grade the sensation as follows: 1) not painful, 2) slightly painful, or 3) very painful. Similarly, 10 patients in Group 2 received a 1.5-J shock with both 50- and 120-μF capacitance in random order before sedation. The patients were then asked to indicate which shock was more painful. After these initial shocks, all patients received sedation with intravenous midazolam and fentanyl.

Statistical analysis. Results are expressed as mean value ± SD. Continuous variables were compared using the two-tailed paired Student *t* test. Multiple comparisons between waveforms were made with the Student-Neuman-Keuls test. Defibrillation efficacy of the biphasic waveforms was compared for leading edge voltage, leading edge current, resistance, pulse duration and stored energy at defibrillation threshold (DFT). Differences were considered statistically significant at $p < 0.05$.

Results

Defibrillation efficacy. *Group 1.* The protocol was successfully completed in all 22 patients. The energy requirements of the 50% tilt biphasic waveform was significantly lower than that for the 65%, 80% and 30%/50% tilt waveforms. There was no significant difference between the 50% and 40% tilt waveforms. The 40%/50% tilt waveform provided slightly lower energy requirements at atrial DFT than the 40% and 50% tilt waveforms. Identical results were observed for peak voltages

Table 2. Atrial Defibrillation Threshold Variables in 22 Patients (Group 1)

Tilt	40%	50%	65%	80%	30%/50%	40%/50%
Energy (J)	1.6 ± 1.2	1.3 ± 0.7*	2.0 ± 1.5	2.2 ± 1.5	2.4 ± 1.6	1.0 ± 0.6†
Voltage (V)	163 ± 58	151 ± 42*	181 ± 64	190 ± 67	201 ± 68	132 ± 39†
Current (A)	3.7 ± 1.3	3.4 ± 1.1*	4.1 ± 1.7	4.2 ± 1.5	4.1 ± 1.2	2.9 ± 1.0†
Impedance (ohms)	47 ± 6.9	47.6 ± 7.1	46.7 ± 6.8	46.1 ± 7	46.3 ± 6.9	48.1 ± 7.3

*$p < 0.01$, 50% versus 65%, 80% and 30%/50%. †$p < 0.05$, 40%/50% versus 50%. Unless otherwise indicated, data presented are mean value ± SD.

and current, as shown in Table 2. The impedances were similar for all waveforms.

Group 2. The protocol was successfully completed in all 16 patients. Table 3 shows the values of the DFT energy, voltage, current, impedance and pulse width for each capacitance. The 50-μF capacitor provided significantly lower energy for atrial defibrillation than the 120-μF capacitance. The peak voltage and current requirements were significantly higher for the 50- than the 120-μF capacitor. Again, there was no statistical difference in impedance between the two capacitances. In addition, a higher capacitance was associated with a significantly longer total shock duration.

In 11 of 16 patients, the 50-μF capacitance waveform provided lower energy requirements at DFT than that for the 120-μF capacitance. Only one patient had a higher DFT energy with 50-μF capacitance than with 120-μF capacitance. In the remaining four patients, the same energy was required to terminate atrial fibrillation.

Pain perception. Of the 15 patients in Group 1 who received a test shock of 0.5 J before sedation, nine (60%) described the shock as very painful, four (26.6%) perceived slight pain, and two (13.3%) experienced no pain.

Of the 10 patients in Group 2 who received test shocks of 1.5 J at different capacitances, six (60%) described both shocks as painful but perceived the 50-μF capacitor shock as more painful ($p < 0.01$), three (30%) perceived both shocks as equally painful, and one (10%) felt no pain from either shock.

Discussion

It is well known that biphasic waveforms decrease shock strength for ventricular defibrillation compared with monophasic waveforms (1–6). Similarly, in both animals and humans, biphasic waveforms have been shown (7,8) to be superior to monophasic waveforms for atrial defibrillation. However, the ideal biphasic waveform remains unknown. The efficacy of a biphasic impulse can be altered by a number of variables, including tilt, capacitance, pulse width and amplitude of each phase. To our knowledge, no human studies to date have addressed the effect of tilt and capacitance on atrial defibrillation success. In addition, whether a significant reduction in the energy required for atrial defibrillation will eliminate the pain perceived with shock delivery is unknown. The results of our studies using a right atrial appendage/coronary sinus catheter system for defibrillation are fourfold: 1) Biphasic waveforms with 50% and 40%/50% tilt provided a significant decrease in energy requirements at atrial DFT compared with 65%, 80% and 30%/50% tilt; 2) a 50-μF capacitor lowered energy requirements for atrial defibrillation compared with a 120-μF capacitor at 65% tilt; 3) shocks delivered from the 50-μF capacitor may be perceived as more painful by patients; and 4) even shocks with energy <1 J can result in considerable discomfort.

Table 3. Atrial Defibrillation Threshold Variables at Each Capacitance in Patients (Group 2)

	Capacitance	
	50 μF	120 μF
Energy (J)	1.4 ± 0.8*	2.0 ± 1.0
Voltage (V)	233 ± 73†	185 ± 51
Current (A)	4.9 ± 1.7‡	3.9 ± 1.2
Impedance (ohms)	49.8 ± 7.6	48.2 ± 7.3
Total pulse width (ms)	5.5 ± 1.2†	13.8 ± 2.1

*$p < 0.03$, †$p < 0.001$, ‡$p < 0.01$, 50 versus 120 μF. Data presented are mean value ± SD.

Effect of tilt. In ventricular defibrillation, the effect of tilt on DFT has been investigated in a number of animal and human studies (9–12). A recent study (11) in humans reported a 39% reduction in DFT energy with a 42%/42% tilt biphasic waveform compared with a 65%/65% tilt biphasic waveform. Similarly, biphasic shocks with 50% tilt in both phases were reported to require less energy for defibrillation than 40%, 65% and 80% tilts (12).

Although the extension of these results on ventricular defibrillation to atrial defibrillation is uncertain, the effect of tilt in our study produced similar findings. The mechanism for different energy requirements between tilts remains unknown. In addition, the optimal duration of the negative phase in relation to the positive phase and the optimal amplitude ratio of the leading edge voltage of the positive and negative phases are unknown in humans. Preliminary data from our institution (13) seem to suggest that the peak voltage and not the duration of the negative phase is important for lowering DFTs. Therefore, biphasic waveforms with a small amplitude of the negative phase and an overall longer duration may provide less efficient defibrillation. In our study, the highest energy at DFT occurred with the 30%/50% biphasic waveform. It is also possible that biphasic waveforms lose their efficacy with tilts ≤30% in the positive phase. This possibility is consistent with previous animal ventricular defibrillation studies (2,14). The 40%/50% biphasic waveform with a slightly smaller tilt in the positive phase than in the negative phase provided the lowest energy for atrial defibrillation. This finding may suggest that in humans the optimal duration of the positive phase is slightly shorter than that in the negative phase. These results conform to recent animal studies (15) in ventricular defibrillation and are consistent with the prediction of Blair's mathematical model.

Effects of capacitance. Theoretical models suggest that optimization of capacitance can lower the DFT (15–18). In addition, mathematical models indicate that capacitors presently incorporated in implantable cardioverter-defibrillators are too large, resulting in a slow decay of voltage and a long pulse duration. Smaller capacitance systems can deliver their charge over a shorter pulse duration, resulting in a steeper voltage decay, a higher leading edge voltage and reduced DFT energies. Because the size of the capacitor is a major determinant of the pulse generator size, a smaller capacitance will decrease the overall size of the implantable cardioverter-defibrillator if less energy is needed for defibrillation.

Both animal and human ventricular defibrillation studies (19,20) have demonstrated significantly lower DFT energy requirements for biphasic waveforms delivered from a capacitor <120 μF. In our study, the 50-μF capacitor at 65% fixed-tilt provided a lower mean stored energy and a higher peak voltage at atrial DFT than the 120-μF capacitor. It seems that a lower capacitance reduces DFT by delivering a waveform with higher peak voltage, higher peak current and shorter duration. Whether biphasic waveforms can be further optimized using a smaller capacitance remains unknown.

Pain tolerance. Because atrial fibrillation is generally well tolerated hemodynamically, patients are likely to be awake at shock delivery; shocks must therefore be perceived as relatively painless. Murgatroyd et al. (21) investigated the tolerability of internal atrial defibrillation in 19 patients using low energy biphasic waveforms through catheters in the right atrium and coronary sinus. Cardioversion was successful in all 19 patients, with a mean energy of 2.16 J and a leading edge voltage of 237 V. The degree of discomfort increased steadily with shock strength in all patients.

Pain from intracardiac electrical shocks is poorly understood. The pain may result from a variety of factors, including stimulation of nerve fibers, contraction of skeletal muscle and psychological components. It has been suggested (22) that the leading edge voltage or the peak current but not the total energy delivered determines the patient's pain perception. Our data confirm this hypothesis. In fact, 6 of 10 patients perceived the shocks delivered from the 50-μF capacitor as more painful than those delivered from the 120-μF capacitor. Although the mean stored energy was lower with the 50-μF capacitor, the leading edge voltage and peak current were significantly higher. Therefore, impulse characteristics may also be an important determinant of pain tolerance. In contrast, in our study even energy of 0.5 J with 120 μF was perceived to be painful by a large proportion of patients. This result indicates that although it is important to reduce the energy required for atrial defibrillation, pain will probably remain an issue that may have to be solved by alternative approaches, such as counseling or shocks at times of higher pain threshold.

Because there are no control data to indicate how frequently induced atrial fibrillation spontaneously terminated, the reliability of using the single lowest value in the measurement of the DFT variables is not as predictable as generation of dose–response curves. However, by requiring 30 s of continuous atrial fibrillation before cardioversion, we believe that spontaneous termination of the induced atrial fibrillation was unlikely to influence our results.

Conclusions. The results of our study suggest that the efficacy of atrial defibrillation can be improved by using biphasic waveforms with 50% tilt in both phases or a 40% tilt in the positive and a 50% tilt in the negative phase. However, the underlying mechanisms for these findings are unknown. We also demonstrated that a smaller capacitor can reduce energy requirements at DFT in a fixed-tilt system by increasing the leading edge voltage and the current and decreasing the pulse width of the waveform. However, even shocks with energy <1 J continue to be perceived as painful.

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